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EXAMINER	
CHONG, KIMBERLY	
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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/646,436
Filing Date: August 21, 2003
Appellant(s): GLEAVE ET AL.

Marina T. Larson
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed October 25, 2006.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is correct.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is correct.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

5989031 CROOKE 4-1999

Rasmusson v. SmithKline Beecham Corp., 413 F. 3d 1318, 1325-26 (Fed. Cir. 2005)

Impax Laboratories v. Aventis Pharamceuticals Inc., 81 USPQ2d 1000 (Fed. Cir. 2006)

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

Claim Rejections - 35 USC § 102

Claims 1-3 and 10-13 are rejected under 35 U.S.C. 102(e) as being anticipated by Monia et al. (US Patent No. 6,383,808)

Claim 1 is drawn to an RNA molecule having a length of less than 49 bases and further targeted to a gene that encodes clusterin. Claims 2-3 limit claim 1 by reciting the RNA molecule has a length of 16 to 29 or 18 to 23 nucleotides in length. Claims 10-13 are drawn to a pharmaceutical composition wherein the pharmaceutically acceptable carrier is a sterile injectable solution and comprising an RNA molecule having a length of less than 49 bases, 16 to 29 bases or 18 to 23 bases targeted to a gene that encodes clusterin.

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) and that is targeted to clusterin mRNA (see Table 1). Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

Thus, Monia et al. anticipates claims 1-3 and 10-13 of the instant application.

Claims 10-11 are rejected under 35 U.S.C. 102(b) as being anticipated by Monia et al. (US Patent No. 6,383,808).

Claims 10-11 are drawn to a pharmaceutical composition wherein the pharmaceutically acceptable carrier is a sterile injectable solution and comprising an RNA molecule having a length of less than 49 bases targeted to a gene that encodes clusterin.

Monia et al. teach an oligonucleotide that can be RNA or a ribozyme (see column 6, lines 37-63) that is targeted to clusterin mRNA (see Table 1). Monia et al. further teach the compounds are preferably from 12 to 30 nucleotides in length (see column 6, lines 54-59). Monia et al. teach a pharmaceutical composition comprising an RNA molecule and wherein the pharmaceutically acceptable carrier is a sterile injectable solution (see column 14, lines 4-10).

Thus, Monia et al. anticipates claims 10-11 of the instant application.

(10) Response to Argument

Appellants traverse the instant rejections under 35 USC § 102 (b) and (e) over Monia et al. It appears appellant's sole argument is that the Monia et al. reference does not anticipate claims 1-3 and 10-13 because Monia et al. does not provide an enabling disclose of a RNA molecule targeted to a gene encoding clusterin.

Appellants assert that because Monia et al. does not disclose even one actual RNA sequence, the reference does not place the public in possession of any embodiment within the scope of the presently claimed invention. Appellants further argue that Monia states in the specification that not all RNA oligonucleotides are effective and therefore examiner has not explained how "the mere statement that RNA species may also exist can be considered an enabling disclosure to those species sufficient for a conclusion of anticipation". From this statement, applicants appear to conclude Monia et al. does not teach any RNA molecule that could target and inhibit expression from a target gene encoding clusterin.

At the outset, Monia et al. does not just make a "mere statement that RNA species may also exist". The statement appellant is referring to (column 6, lines 37-40) is a definition of the term "oligonucleotide" and therefore every time the term oligonucleotide is mentioned in the specification, the specification is referring to RNA oligonucleotides and DNA oligonucleotide. Monia et al. clearly teach oligonucleotides that target and inhibit clusterin expression. While it is true that Monia et al. do not teach an actual RNA sequence, it must be noted that the claims at issue do no recite an actual RNA sequence (see for example, claim 1). Further, it is routine to one of skill in

the art to make and use RNA oligonucleotides to target and inhibit gene expression. Monia et al. clearly teach said inhibitory oligonucleotides are routinely RNA or DNA molecules, as known in the art. Therefore, Monia et al. is an anticipatory reference because it teaches all the limitations of the instantly claimed invention. Further, as sated above, the use of RNA oligonucleotides to mediate degradation is routine to one of skill in the art, as evidenced by US Patent No. 5,898,031 referred to hereinafter the "031 Patent". The '031 Patent teach RNA oligomers work to inhibit target gene expression (see Figures 2 and 3). Figures 2 and 3, as well as Example 22 teach that RNA oligonucleotides targeted to a Ras-oncogene efficiently mediate degradation of the target RNA in cells, and thus demonstrates the routine nature of using RNA oligonucleotides to target a gene and inhibit gene expression.

Moreover, it is difficult to conceive appellant's position that the Monia et al. reference is not enabled. The enablement requirement for a prior art reference to be anticipatory under 35. U.S.C. 102 has been clearly set out in Rasmusson v. SmithKline Beecham Corp., 413 F. 3d 1318, 1325-26 (Fed. Cir. 2005). The Court stated in Rasmusson, "[A] prior art reference need not demonstrate utility in order to serve as an anticipating reference under section 102." This standard of enablement of a prior art reference for purposes of anticipation was reiterated in Impax Laboratories v. Aventis Pharamceuticals Inc., 81 USPQ2d 1000 (Fed. Cir. 2006). Here, the court stated, "anticipation does not require actual performance of suggestions in a disclosure. Rather, anticipation only requires that those suggestions be enabled to one of skill in the art."

Accordingly, because Monia et al. teach oligonucleotides that target and inhibit clusterin gene expression and further teach said oligonucleotides can be RNA and further because it was routine to make and use RNA molecules to target and inhibit gene expression, Monia et al. anticipates claims 1-3 and 10-13 of the instant application.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Kimberly Chong

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